

# Notice of Allowability

## Application No.

09/881,012

## Examiner

Jeanine A Goldberg

## Applicant(s)

GINNS ET AL.

## Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/2/04; 7/6/04.
2. ☒ The allowed claim(s) is/are 28-39.
3. ☒ The drawings filed on 10 September 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*J. Goldberg*  
**JEANINE A. GOLDBERG**  
**PATENT EXAMINER**

### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance.

The claims have been amended to specifically indicate that the claims are drawn to screening methods for markers located between D4S431 and D4S404 which are associated with increased resistance to familial bipolar affective disorder. By amending the claim language to no longer require using a marker associated with resistance to bipolar affective disorder, the claims are directed to the screening method as argued extensively throughout the responses previously filed. This clarification overcomes the enablement rejection previously of record because the claims no longer require using a marker known to be associated with increased resistance to BAPD. Instead, the allowed claims are drawn to methods for screening to identify such makers. The specification teaches that the region recited in claim 1(a) comprises 19 markers that exhibits significant linkage to resistance to BAPD (see arguments of June 3, 2004, page 10). Further Appendix A, of the response filed June 3, 2004, provides a list of markers and their association which was taken from Figure 6 and 7 (see arguments of June 3, 2004, page 14). There would have been a reasonable expectation of success that screening for additional markers within this associated region would yield additional markers. At the time the invention was made, it would have been routine to select markers from a chromosomal region between D4S431 and D4S404. Thus, a method of screening these markers using a well known methodology for association would have been routine. The art, however, fails to direct the ordinary artisan to this particular region between D4S431 and D4S404 because at the time the application was filed there were no known markers within this region that were associated with resistance to BAPD. Thus, the method of screening this region for additional

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mutations/markers/genotypes associated with increased resistance to familiar bipolar disorder would not have been fairly suggested or taught in the prior art.


2. It is noted that the petition decided on September 4, 2004, has been granted and the first line of the specification including the specific relationships between the applications cited has been entered.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Jeanine Goldberg**  
**Patent Examiner**  
September 14, 2004